

### REMARKS

Claims 1-34 were pending in the present application. No claims have been amended. Claim 9 was previously cancelled in the Amendment filed October 4, 2005. No new claims have been added. Further, no new matter has been added.

Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented, or an abandonment of any unclaimed subject matter.

### *General Remarks*

Examiner Patel did not fully respond to the arguments and amendments made in the Applicant's response to the non-final Office Action of April 5, 2005 (which were submitted on October 4, 2005).

In particular, Examiner Patel did not respond to the Applicant's arguments with respect to claims 20-23 and 24-25. Examiner Patel has rejected all of the pending claims over a single reference, U.S. 4,601,465 to Roy ("Roy"). As described in the Applicant's response of October 4, 2005 (and elaborated below), the Roy does not show at least one feature recited in claims 20-25, and therefore cannot anticipate these claims, as Examiner Patel asserts. In particular, Roy does not show a valve enclosed by a mouthpiece. The Examiner appears to have ignored this claim feature entirely.

Examiner Patel also did not fully respond to the Applicant's arguments and amendments to claims 1-19. In responding to the Office Action of April 5, 2005, the Applicant pointed out that Roy describes a device with an elongated body that projects substantially from the subject's mouth, and that this device is significantly different from the Applicant's claimed invention which does not project substantially from the subject's mouth. The Applicant also amended claims 1 and 8 to clarify this structural difference between Roy and the device of the pending application. Examiner Patel argues that this is merely a "recitation of intended use" and does not result in a structural

difference. This cannot be true. A device which fits substantially within a patient's mouth is structurally different from a device that does not fit substantially within a patient's mouth.

These points are addressed in further detail below.

***Claim Rejection Under 35 U.S.C. § 102(b)***

Claims 1-10, and 12-25 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Roy.

The Applicant respectfully disagrees. Roy does not include all of the features that are recited in each of claims 1-10 and 12-25. A reference must disclose a device having *all* features of a claimed device in order to anticipate a claim. MPEP §2131.

First, independent claim 1 (from which claims 2-7 depend), and independent claim 8 (from which claims 9-19 depend) recite devices that *fit substantially within a patient's mouth* (oral cavity). In contrast, Roy shows devices that do not fit substantially within a mouth, but extends out of the mouth for a significant distance because they include a long tubular body specifically to project from the mouth, at the end of which is located a valve.

Second, independent claim 20 (from which claims 21-23 depend), and independent claim 24 (from which claim 25 depends) recite devices having a housing to be held within a patient's mouth, where the housing (or mouthpiece) encloses a valve. Roy does not show a mouthpiece enclosing a valve where the region enclosing the valve is configured to be held in a wearer's mouth. In fact, Roy teaches only locating a valve far from the wearer's mouth, separated from the mouth by an elongated "tubular body." See at least column 1, line 61-col. 2, line 25 and figures 1-3, 5 and 7.

Each of these claims is considered in more detail below.

*Claims 1-7*

Independent claim 1 recites a device that *fits substantially within a patient's mouth*. Roy does not show or describe a device that fits *substantially within* a patient's mouth. Only a small portion of Roy's device (the mouthpiece) fits within a user's mouth. Roy's device has an elongated body that extends from a user's mouth. Although Roy's device can include a mouthpiece, the mouthpiece is located at one end of the long tubular body that extends from the mouthpiece and away from a wearer's mouth. See, e.g., Roy's abstract ("A tubular body defining an air duct is connected at one end to the mouth-piece or to the mask with the air duct in alignment and communication with the opening."). See also, Roy, col. 2, lines 1-6, and figures 1-9. The long tubular body projects from the user's face. See Roy, figs. 1, 5, and 7. Thus Roy's device does not fit substantially within a patient's mouth since the majority of the device (e.g., the body of the device) projects from the user's face.

Roy also emphasizes that it is important that the device includes this long tubular body. According to Roy: "A very important advantage of the device according to the invention is that the dead space provided by the passages and ducts 3, 5, 7 or 32 between the mouth-piece 9 or mask 43 and the obstruction means 17 and 33, substantially increases the dead respiratory volume of the user." Roy, col. 6, lines 42-54. See also, Roy's abstract, "Proper stimulation is obtained when use is made of a tubular body long enough to increase the dead space of the respiratory system of the person using the device."

In the final Office Action of December 28, 2005, Examiner Patel argues that "the Applicant has not limited the recitation to how much of the device fits within the mouth, i.e., the term substantially is a broad recitation and as such the Roy reference teaches a device that fits substantially within the mouth." While it may be true that the term "substantially" is broad, this breadth does allow the Examiner to ignore it as a feature of the claim. See MPEP §2111; see also MPEP §2173.05(b)(D). In this case, the device shown in Roy does not fit "substantially within the mouth" as this feature would be clearly understood by one of skill in the art reading the pending claims. Broad claim terms such as "substantially within" are permissible terms, and the applicant

should not be required to narrow them where (as here) they are definite and clear, and they further distinguish the recited device from prior art. See, e.g., *Ecolab, Inc. v. Envirochem, Inc.* 264 F. 3d at 1365-66 (Fed. Cir. 2001); See, e.g., *Andrew Corp. v. Gabriel Elecs. Inc.*, 847 F.2d 819, 821-22, (Fed. Cir. 1988); *Pall Corp. v. Micron Seps.*, 66 F.3d 1211, 1217, 36 USPQ2d 1225, 1229 (Fed. Cir. 1995).

Examiner Patel also argued that the limitation “configured to fit substantially within...” is merely “an intended use” and does not result in a structural difference. This is incorrect. A device that is ‘configured to fit substantially within a subject’s mouth’ is observably structurally different from the devices shown in Roy which are not configured to fit substantially within the subject’s mouth, and are, in fact, configured to project a substantial distance from the subject’s mouth. Roy shows and teaches exercise devices that have a mouthpiece (or facemask), tubular body connected to the mouthpiece “at one end” of the mouthpiece, and an “obstruction means” mounted “within the tubular body at the other end.” See at least column 1, line 61-col. 2, line 25 and figures 1-3, 5 and 7. The written description of Roy, as well as every single figure in Roy show a device in which a mouthpiece to be held in the wearer’s mouth is attached to an extended tubular body at the end of which is an obstruction means (e.g., providing resistance).

Examiner Patel further argues that “[i]f the prior art structure is capable of performing the intended use, then it meets the claim.” Roy is manifestly NOT capable of being “configured to fit substantially within the subject’s mouth” as recited by claims 1-7 and 8-19. First, it is clear from the figures and detailed description that Roy’s device has a mouthpiece to be held in the wearer’s mouth, and the rest of the device (e.g., the tubular body) projects out from the wearer’s mouth. Only the mouthpiece of Roy is configured to fit within the wearer’s mouth. See, e.g., Figures 1 to 4 of Roy, and col. 4, lines 11-28 (“The body 1 is provided at one end with a mouthpiece 9 capable being inserted in the mouth of the user of the device. This mouth-piece comprises a thin, slightly curved element 11 made of semi-flexible material, which element is intended to be inserted between the lips and the gums and teeth of the user. The element 11 comprises a central opening 13 which is in alignment and direct communication with the inlet opening of the air duct 3. Two L-shaped projection are provided on both side of the opening 13, for insertion between the teeth of the user.

These projections advantageously cooperate with the element 11 to keep the device according to the invention rigidly in position in the mouth of the user.”). Second, the devices taught by Roy may not even fit within the wearer’s mouth, would be unlikely to work if they were physically forced into a wearer’s mouth, and if a device as taught by Roy were held “substantially within the wearer’s mouth” the device would likely choke and injure the wearer.

Thus, since Roy’s device is not configured *to fit substantially within a patient’s mouth* as recited by claims 1-7, Roy does not anticipate claims 1-7. The 35 U.S.C. §102(b) rejection of claims 1-7 should be withdrawn for at least this reason. The Applicant respectfully requests withdrawal of the 35 U.S.C. §102(b) rejection of claims 1-7.

#### *Claims 8-19*

Independent claim 8 recites a device comprising a body configured to *fit substantially within a patient’s mouth*. As described above, Roy does not show or describe a device that fits *substantially within* a patient’s mouth, as recited in the claims. The devices described by Roy are instead configured to project from the user’s face. In particular, Roy’s device has a long tubular body that projects from the subject’s mouth or face.

Since Roy does not show or describe a device that is configured to fit substantially within a patient’s mouth, Roy cannot anticipate claims 8-19. The 35 U.S.C. §102(b) rejection of claims 8-19 should be withdrawn. The Applicant respectfully requests withdrawal of the 35 U.S.C. §102(b) rejection of claims 8-19.

#### *Claims 20-23*

Independent claim 20 recites a “housing configured to be held in a patient’s mouth, the housing enclosing at least one valve.” Roy does not show or describe a valve enclosed by a housing configured to be held in a patient’s mouth. Instead, Roy describes a check valve (or valves) located at the opposite end of the device, away from the region of Roy’s device configured to be held in the wearer’s mouth. Thus, Roy’s check-valve is not enclosed by a housing configured to be held in a

patient's mouth. Roy's valve is separated from a mouthpiece by a passage or duct, creating a dead space between the mouthpiece and the valve. See Roy, Abstract ("A tubular body defining an air duct is connected at one end to the mouth-piece or to the mask with the air duct in alignment and communication with the opening. The device also comprises a membrane mounted in the tubular body *at the other end thereof*," emphasis added).

Thus, Roy cannot anticipate claims 20-23. The 35 U.S.C. §102(b) rejection of claims 20-23 should be withdrawn. The Applicant respectfully requests withdrawal of the 35 U.S.C. §102(b) rejection of claims 20-23.

*Claim 24 and 25*

Independent claim 24 recites a means *on a mouthpiece* for causing an air flow resistance to expiration that is greater than an air flow resistance to inspiration. As already described above, Roy does not show or describe a means *on a mouthpiece* for causing an air flow resistance to expiration that is greater than an air flow resistance to inspiration. The valve (airflow resistor) shown and described in Roy is separated from the mouthpiece by an elongated body.

Thus, Roy's obstruction means is not on a mouthpiece, as recited by claims 24 and 25, and therefore Roy cannot anticipate claims 24 and 25. The 35 U.S.C. §102(b) rejection of claims 24 and 25 should be withdrawn. The Applicant respectfully requests withdrawal of the 35 U.S.C. §102(b) rejection of claims 24 and 25.

***Claim Rejection Under 35 U.S.C. § 103(a)***

*Claim 11*

Claim 11 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Roy. According to the Office Action:

"As to Claim 11, Roy teaches essentially all of the limitations except for wherein the body comprises at least one concave channel configured to receive a patient's teeth. Roy, rather

teaches elements 15 as shown in Figure 1 to bite onto by a patient's teeth. One of ordinary skill in the art at the time of the invention would expect Roy's device to work equally as well as the Applicant's device since both would perform the function of retaining the device in the patient's mouth." Office Action of April 5, 2005, page 7.

The Applicant respectfully disagrees. As described above, Roy does not describe all of the features of claim 8, from which claim 11 depends. In particular, Roy does not show or describe a valve device that is *configured to fit substantially within a patient's mouth*, as recited by the claims. Furthermore, even modifying element 15 of Roy to describe a concave channel cannot cure this deficiency. In order to establish obviousness, a reference (of combination of references) must teach or suggest all the features of the claim. MPEP §2142.

In this case, not only is Roy missing a feature recited in the claims, but Roy explicitly teaches away from including this feature. As described above, Roy describes an elongated body (resulting in increased "dead space") as a "very important advantage." Roy, col. 6, lines 42-54. The bulk of Roy's device (the elongated tubular body) is not held within the subject's mouth, but projects from the subject's mouth.

Thus, claim 11 cannot be obvious from Roy, because Roy does not teach or suggest all of the features of the claim. The 35 U.S.C. §103(a) rejection of claim 11 should be withdrawn. The Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) rejection of claim 11.

### ***Double Patenting***

#### ***Claim 24***

Claim 24 stands rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,722,360.

Applicants respectfully disagree. Under the one-way test for obvious-type double patenting, the pending claims must be obvious in light of the claims of the parent case, U.S.

6,722,360. MPEP §804. In this case, claim 24 is not an obvious variation over the claims of U.S. 6,722,360, including claim 5 of U.S. 6,722,360. Pending claim 24 was amended during prosecution to recite “a mouth piece configured to be held *substantially entirely* within the patient’s mouth.” Claim 5 of U.S. 6,722,360 does not teach or suggest this feature, nor is this an obvious variation.

Thus, the Applicant respectfully requests withdrawal of the obvious-type double patenting rejection of claim 24, and allowance of all of the pending claims.



**CONCLUSION**

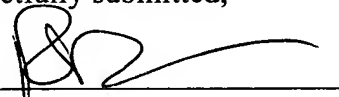
In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **606492000201**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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